



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/220,175	03/30/94	ANDERSON	W 27101097

18M2/0907

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STONE, J. EXAMINER

ART UNIT	PAPER NUMBER
1804	5

09/07/94

DATE MAILED:

NOTICE OF ALLOWABILITY

PART I.

- ☒ This communication is responsive to Applicants' amendment 5/16/94; declaration 8/16/94
- ☒ All the claims being allowable. PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
- ☒ The allowed claims are 27-40
- ☐ The drawings filed on \_\_\_\_\_ are acceptable.
- ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [ ] been received. [ ] not been received. [ ] been filed in parent application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_.
- ☐ Note the attached Examiner's Amendment.
- ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
- ☒ Note the attached Examiner's Statement of Reasons for Allowance.
- ☒ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
- ☒ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- ☒ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
  - ☒ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. \_\_\_\_\_. CORRECTION IS REQUIRED.
  - ☐ The proposed drawing correction filed on \_\_\_\_\_ has been approved by the examiner. CORRECTION IS REQUIRED.
  - ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
  - ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ☐ Examiner's Amendment
- ☐ Examiner Interview Summary Record, PTOL-413
- ☒ Reasons for Allowance
- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Citation, PTO-1449

- ☐ Notice of Informal Application, PTO-152
- ☒ Notice re Patent Drawings, PTO-948
- ☐ Listing of Bonded Draftsmen
- ☐ Other

*J Stone*  
JACQUELINE STONE  
PRIMARY EXAMINER  
ART UNIT 1804

SN 08/220,175

PTOL-37 (REV. 4-89) \*

USCOMM-DC 89-3789

Serial No. 08/220,175

-2-

Art Unit 1804

The following is an Examiner's Statement of Reasons for Allowance:

The instant claims are the same as those allowed in parent application Serial No. 07/904,662. The Information Disclosure Statement filed March 30, 1994 has been considered. The documents submitted to the Recombinant DNA Advisory Committee which constitute clinical proposals of the inventors, and which indicate that whether or not a therapeutic outcome would be realized was unknown, do not represent prior public knowledge of the claimed invention which constitutes applicable prior art. At the time of filing of the instant specification it was neither known nor predictable that a gene, transfected into human cells in vitro, would cause those cells to express therapeutically relevant amounts of protein and thereby alleviate a disease. As evidenced by the declaration and articles submitted on form PTO-892, which were of record in the parent application, up to the time the inventors conducted th human treatments, success was not known and not predictable or reasonably expected; in fact, skepticism in the art ran quite high. Thus, the prior art does not teach or suggest the subject matter of the instant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on

7/

5

Serial No. 08/220,175

-3-

Art Unit 1804

Statement of Reasons for Allowance."

Jacqueline Stone

August 29, 1994

*Stone*  
JACQUELINE STONE  
PRIMARY EXAMINER  
ART UNIT 1804

12

5



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**NOTICE OF ALLOWANCE  
AND ISSUE FEE DUE**

- ☐ Note attached communication from the Examiner  
☐ This notice is issued in view of applicant's communication filed \_\_\_\_\_

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/220,175	03/30/94	014	STONE, J	1804 09/07/94
First Named Applicant	ANDERSON, W. FRENCH			

TITLE OF INVENTION: **GENE THERAPY**

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 27101097	424-093.210	E19	UTILITY	NO	\$1170.00	12/07/94

**THE FEE DUE IS THE AMOUNT IN EFFECT AT THIS TIME. IF THE AMOUNT OF THE ISSUE FEE INCREASES PRIOR TO PAYMENT, APPLICANT WILL BE NOTIFIED OF THE BALANCE OF ISSUE FEE DUE.**

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.**

**PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

- I. Review the SMALL ENTITY Status shown above.  
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
  - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
  - B. If the Status is the same, pay the FEE DUE shown above.
- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.
- III. All communications regarding this application must give series code (or filing date) and serial number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to contrary.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

**IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**